AUROQUIL COLD AND FLU NIGHTTIME RELIEF - acetaminophen, doxylamine succinate, and dextromethorphan hbr solution
Aurohealth LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients (in each 30 mL dose cup)	**Purpose**
Acetaminophen, USP 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr, USP 30 mg	Cough suppressant
Doxylamine succinate, USP 12.5 mg	Antihistamine

Uses

temporarily relieves common cold/flu symptoms:
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take
- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Allergy alert: acetaminophen may cause severe skin reactions.
Symptoms may include:
- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a

doctor or pharmacist before taking this product.
- to make a child sleep

Ask a doctor before use if you have
- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are
- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product
- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if
- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
- take only as directed – see Overdose warning
- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses (120 mL) (8 TBSP) per 24 hours
- mL = milliliter; TBSP = tablespoon

adults & children 12 years & over	30 mL (2 TBSP) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

- **when using other Daytime or Nighttime products, carefully read each label to insure correct dosing**

Other information

- **each 30 mL dose cup contains:** potassium 5 mg, sodium 38 mg
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

acesulfame potassium, alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavors, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or Comments?

1-855-274-4122

Distributed by:
Aurohealth LLC.
2572 Brunswick Pike
Lawrenceville, NJ 08648

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 6 FL OZ (177 mL Bottle)

AUROHEALTH

Compare to the active ingredients
in Vicks® NyQuil® Cold & Flu*

NDC 58602-136-18

AuroQuil
COLD & FLU
Nighttime Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains:
650 mg - **Acetaminophen** USP (Pain reliever/fever reducer)
12.5 mg - Doxylamine succinate USP (Antihistamine)
30 mg - Dextromethorphan HBr USP (Cough suppressant)

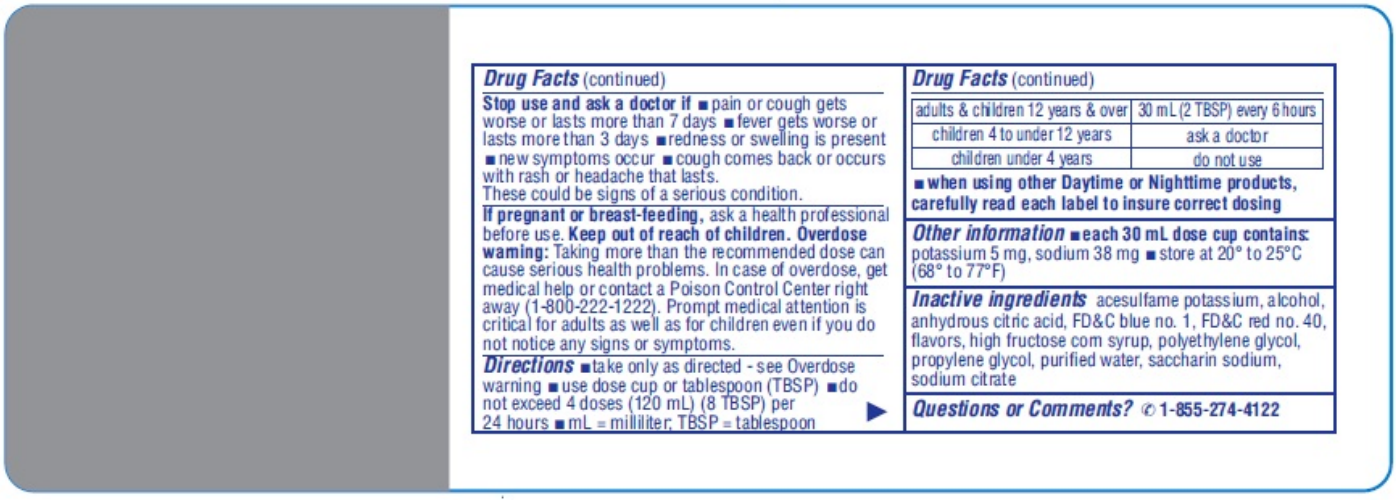
- **Aches, Fever & Sore Throat**
- **Sneezing, Runny Nose**
- **Cough**

Alcohol 10% **6 FL OZ (177 mL)**

Front

Back

Bottom Ply



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 8 FL OZ (237 mL Bottle)

AUROHEALTH

Compare to the active ingredients
in Vicks® NyQuil® Cold & Flu*

NDC 58602-136-20

AuroQuil
COLD & FLU
Nighttime Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains:
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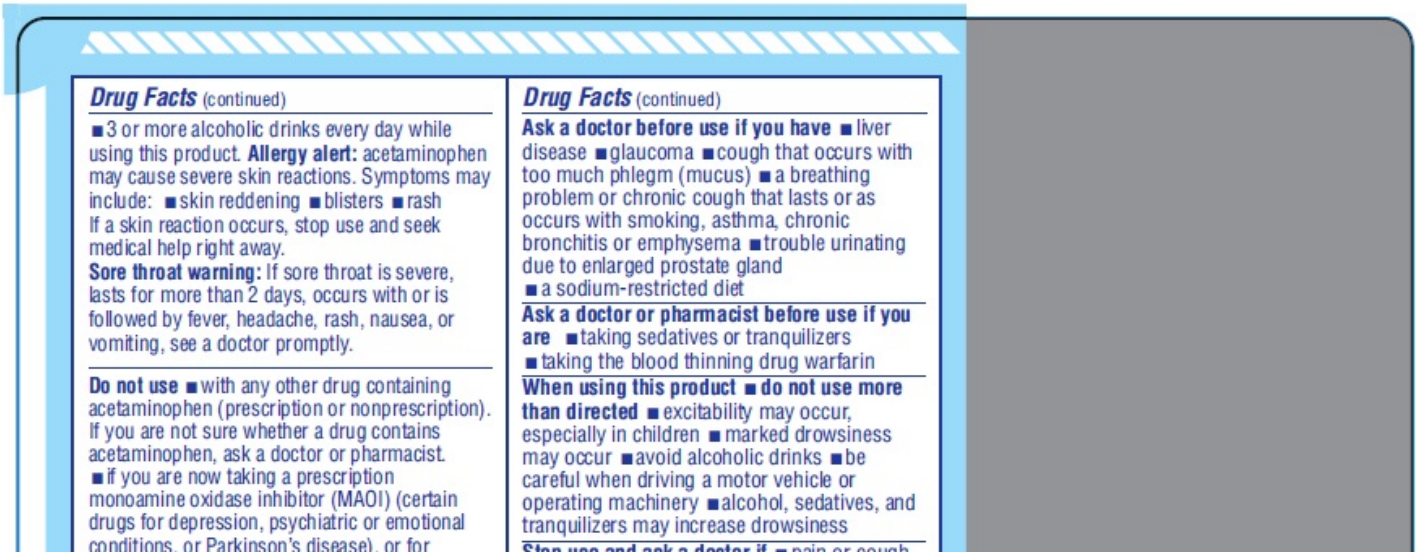
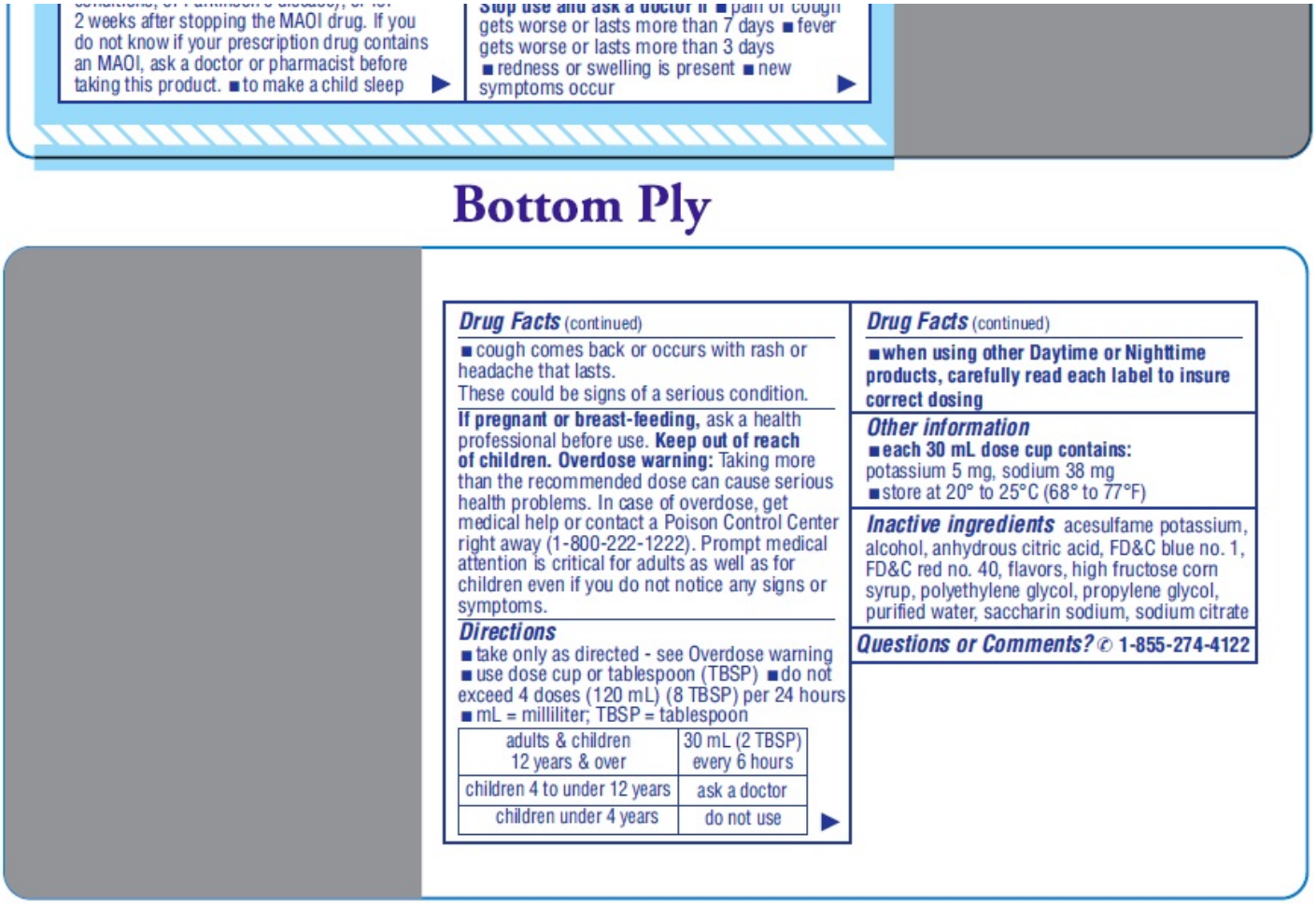
- **Aches, Fever & Sore Throat**
- **Sneezing, Runny Nose**
- **Cough**

Alcohol 10% **8 FL OZ (237 mL)**

Front

Back





PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 12 FL OZ (355 mL Bottle)

AUROHEALTH

Compare to the active ingredients
in Vicks® NyQuil® Cold & Flu*

NDC 58602-136-16

AuroQuil
COLD & FLU
Nighttime Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains:
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- **Aches, Fever & Sore Throat**
- **Sneezing, Runny Nose**
- **Cough**

Alcohol 10% **12 FL OZ (355 mL)**

Front

Front

Tamper Evident: Do not use if printed shrinkband is missing or broken.
Failure to follow these warnings could result in serious consequences

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil® Cold & Flu

Distributed by:
Aurohealth LLC.
2572 Brunswick Pike
Lawrenceville, NJ 08648

3001000359

LOT:
EXP:

AUROHEALTH

Compare to the active ingredients in Vicks® NyQuil® Cold & Flu*

NDC 58602-136-16

AuroQuil

COLD & FLU

Nighttime Relief

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12 FL OZ (355 mL)

Lift Here for Drug Facts

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Drug Facts (continued)

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Bottom Ply

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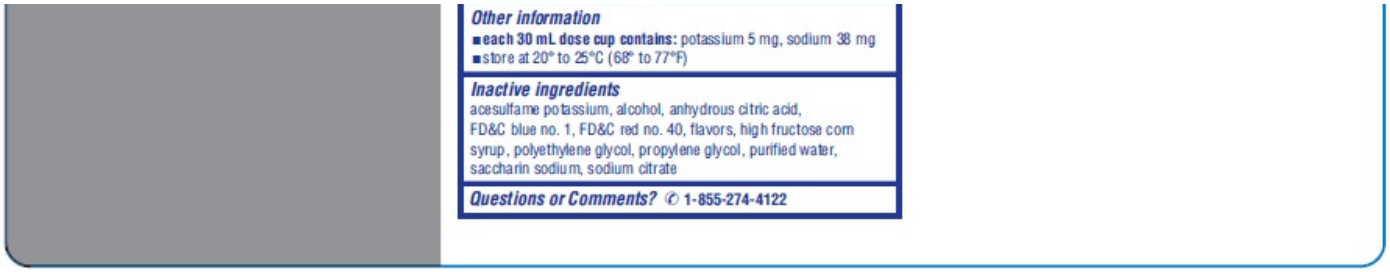

AUROQUIL COLD AND FLU NIGHTTIME RELIEF

acetaminophen, doxylamine succinate, and dextromethorphan hbr solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-136
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CHERRY (UNII: BUC5I9595W)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	RED	**Score**	
Shape		**Size**	
Flavor	CHERRY, MENTHOL	**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-136-18	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2015	09/01/2021
2	NDC:58602-136-20	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2015	09/01/2021
3	NDC:58602-136-16	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2015	09/01/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/27/2015	09/01/2021

Labeler - Aurohealth LLC (078728447)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurohealth LLC		078728447	MANUFACTURE(58602-136)

Revised: 11/2020 Aurohealth LLC